

14. (Amended) A dosage form intended for direct oral administration, comprising:  
an effective amount of at least one drug, said drug present in the cores of coated particles, said cores including a taste masking layer composed of a material which is generally insoluble in saliva at a neutral to basic pH and completely soluble in saliva at a pH of less than about 6.5; and  
a spacing layer surrounding said core and substantially completely sequestering said core from said taste masking layer and being capable of rapidly exposing said core when exposed in the stomach of a patient; said taste masking layer preventing exposure of said spacing layer in the mouth of a patient for a period of at least about 20 seconds after being placed into the mouth and being capable of rapidly exposing said spacing layer when in the stomach of a patient; and  
at least one pharmaceutically acceptable excipient provided in an amount of between greater than zero and less than 100%, based on the weight of the finished dosage form.

Please cancel claims 2, 3, 19 and 20 without prejudice or disclaimer.

#### REMARKS

Entry of the foregoing and reexamination and reconsideration of the above-captioned application, pursuant to and consistent with 37 C.F.R. § 1.112 are respectfully requested. The claims have been rejected pursuant to 35 U.S.C. § 102(b) or, in the alternative, as obvious pursuant to 35 U.S.C. § 103(a) over Kais, U.S. Patent No. 5,516,524 ("the '524 patent"). As that rejection will be applied to the claims as amended, applicants respectfully traverse.

Applicants believe that the present invention is neither anticipated nor obvious over the '524 patent, even prior to the proffered amendments. The Patent and Trademark Office relies on the '524 patent to teach that double coatings are possible for the purpose of eliminating the bitter taste of a drug, that two different materials can be used for each of the coatings in the double coating system and that a pH sensitive polymer may be selected. However, as originally filed, the claimed invention required the use of a pH sensitive material as a taste masking layer. It also teaches and claims that the taste masking layer is the second layer and is separated from the core by an interspersed spacing layer. While the '524 patent does appear to disclose the possibility of a double layer taste masking coating system and the use of a pH sensitive material as the examiner suggests, the only relevant example, Example VII, indicates the use of a pH sensitive material as part of the coating system for the internal layer, the layer analogous to the spacing layer rather than the taste masking layer. The undersigned has reviewed the '524 patent and has been unable to find anything

specifically suggesting that when a double coating system is used, it is the outermost layer which is pH sensitive.

In addition, while the '524 patent does identify certain types of Eudragit as being pH sensitive polymers useful in accordance with their objectives, they also note at column 5, lines 44-49 that the pH sensitive polymers used, as well as gum coatings used, preferably dissolve under basic environments of the small intestines. The claimed taste masking layer, however, is generally insoluble at roughly neutral and basic pHs and instead is geared to expose its contents, namely the spacing layer coated core, when placed in acid environments.

The differences in the materials contemplated for the coatings and their arrangement is much more than merely happenstance. The '524 patent could not possibly teach or suggest the claimed invention. To do so, one would have to take the pH sensitive materials disclosed in the '524 patent and use them as the outer coating material. However, since the '524 patent discloses that these materials are pH sensitive and are soluble at basic pHs, they would defeat the purpose of the taste masking layer in accordance with the claimed invention. They would, in essence, be rapidly soluble in the mouth, not insoluble as the claimed invention requires.

For many of these same reasons, the claimed invention is not rendered obvious. Indeed, the '524 patent contains no teaching for placing the pH sensitive coating material on the outer periphery of the formulation nor does it disclose the need and desirability of using a material which is relatively unreactive in neutral to basic pHs as the outer material. In addition, the reference clearly suggests the design of a formulation which will dissolve in the intestines to release the drug. The claimed invention requires release in the stomach. Accordingly, the '524 patent actually teaches away from the claimed invention.


Notwithstanding these observations, applicants have combined claims 2 and 3 with claim 1 and made similar amendments to claim 14 and have canceled the appropriate dependent claims. It is believed that these amendments do nothing more than accentuate the differences between the claimed invention and the '524 patent by making it clear that the taste masking material will rapidly expose the spacing layer when placed in the stomach and that the spacing layer will rapidly expose the core when it is placed in the stomach. Nothing in the '524 patent teaches or suggests the rapid exposure of either the inner layer or the core in the stomach, nor suggests that this process should occur rapidly such that the drug can be released into the stomach. Accordingly, the claimed invention as amended is neither anticipated nor rendered obvious by the '524 patent.

Should the examiner have any questions with regard to the foregoing, the examiner is encouraged to contact the undersigned, at the examiner's convenience, at 908 654 5000. Furthermore, if there are any additional charges in connection with this requested amendment, the examiner is authorized to charge Deposit Account No. 12-1095 therefor. A two-month extension of time is being submitted concurrently herewith.

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order and such action is earnestly submitted.

Respectfully submitted,

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